

# ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

Section Editor: John Baillie, MB ChB, FRCP

## EUS-Guided Drainage of Pancreatic Fluid Collections Using Fully Covered Self-Expandable Metal Stents



**Kenneth F. Binmoeller, MD**  
 Director, Interventional Endoscopy Services  
 Paul May and Frank Stein Interventional Endoscopy Center  
 California Pacific Medical Center  
 San Francisco, California

**G&H** What criteria are required for performing endoscopic drainage of pancreatic fluid collections?

**KB** Endoscopic treatment of pancreatic fluid collections involves internal drainage of the collection into the bowel lumen. Historically, in order to perform endoscopic drainage, 3 conditions have to be met. First, the fluid collection has to be reasonably mature (ie, it has to have a well-defined wall and be primarily liquid in content). Second, the wall of the fluid collection has to be adherent to the bowel lumen (unlike Figure 1, which shows a fluid collection with poor adherence). Third, the fluid collection has to be a reasonable size (generally >6 cm).

**G&H** How is endoscopic drainage traditionally performed?

**KB** The first step of endoscopic drainage is to access the fluid collection, either endoscopically or under endoscopic ultrasound (EUS) guidance. If there is a prominent extrinsic compression of the fluid collection against the wall, the endoscopist can easily identify the collection endoscopically and can use a needle or cautery device to access the collection by transmural puncture. If the fluid collection does not create a prominent extrinsic compression (ie, there is no “bulge” on endoscopic examination), EUS can be used to visualize the collection. Under EUS guidance, the endoscopist can puncture the fluid collection and then insert a stent for drainage into the bowel lumen.

The next step of standard endoscopic drainage is to place a guide wire into the fluid collection and then per-



**Figure 1.** An endoscopic ultrasound showing poor adherence of a fluid collection to the stomach wall. The arrow indicates an echogenic layer (fat) interposed between the 2 walls.

form a dilation (typically with a balloon) to enlarge the transmural tract (usually up to 8 mm) for the insertion of stents. The last step of drainage is to place 2 or 3 plastic stents, side by side, to drain the collection through the stent lumen as well as alongside the stents.

**G&H** Can metal stents be used in this setting?

**KB** Recently, fully covered self-expandable metal stents (FCSEMS), which have much larger lumens than those of plastic stents, have been used to drain fluid collections (Figure 2). A FCSEMS is used if the contents of the collection are thick, necrotic, or infected, as these collections may not adequately drain through plastic stents.



**Figure 2.** Radiography showing a fully covered self-expandable metal stent (FCSEMS) draining a fluid collection. The arrow indicates a “waist” where the FCSEMS traverses the wall.

### G&H How are fluid collections with necrosis, including walled-off pancreatic necrosis, usually treated?

**KB** In the typical evolution of fluid collections, there is a large amount of necrosis early on, and then over time the necrosis liquefies. This process can take many weeks, sometimes months. When patients have necrotizing pancreatitis, the necrosis becomes walled-off and is called walled-off pancreatic necrosis (WOPN). This is not a pseudocyst because a pseudocyst is defined as a mature fluid collection without necrosis that is at least 4 weeks old.

It is now possible to treat WOPN with endoscopic necrosectomy, whereby the endoscopist enters the cystic cavity and removes necrosis with standard extraction tools. This allows the endoscopist to treat fluid collections at an earlier stage, when variable degrees of necrosis are present. However, WOPN may lack adherence to the enteric wall because it is less mature than a pseudocyst. This raises a new challenge, in which endoscopists are confronted with a higher risk of perforation and leakage. As mentioned, a lack of adherence has historically been considered to be a contraindication to endoscopic drainage of fluid collections.

### G&H Are there ways to reduce the risks of perforation and leakage?

**KB** Minimizing tract dilation and sealing the tract by placing a FCSEMS should reduce the risks of perforation and leakage. My colleagues and I recently conducted a pilot study to evaluate a strategy for eliminating tract dilation and placing a FCSEMS to prevent perforation in patients with poorly adherent fluid collections.



**Figure 3.** A gastrocystostomy tract after removal of a fully covered self-expandable metal stent, enabling endoscopic necrosectomy.

### G&H What was the design of this study?

**KB** Study participants had to have pancreatic fluid collections that were symptomatic, were larger than 6 cm in diameter, and had indeterminate adherence. This last criterion was evaluated by EUS and meant that the patients had to have an echogenic layer visualized between the bowel wall and the cyst wall at the point of maximal contact and/or separation of the bowel wall and the cyst wall by more than 1 cm.

We used a novel one-step access device (Navix, Xlumena Inc.) to enable access to the fluid collection and the creation of a tract large enough for the immediate insertion of the FCSEMS delivery catheter, without the need for tract dilation. Rather than a needle, a lumenless trocar was used for puncture. The catheter was advanced over the trocar into the fluid collection, and the trocar was removed. The lumen of the catheter enabled diagnostic interventions, such as fluid sampling and injection of contrast, and insertion of a guide wire. This catheter was then exchanged over the wire for the delivery catheter of a FCSEMS, which was subsequently deployed. Patients returned in 7–10 days for stent removal, and, if necessary, dilation was performed to enter the cavity with the endoscope for necrosectomy (Figure 3).

### G&H What were the study findings and conclusions?

**KB** Of the 18 patients entered in the study, 16 underwent necrosectomy 7–10 days after the initial procedure. Five of these required additional procedures with stent exchanges, and 3 patients were eventually referred to surgery because their fluid collections failed to fully resolve. Fluid collections fully resolved in 14 patients, with a median time to resolution of approximately 2 months.

### G&H How significant of a concern is migration of these stents?

**KB** Stent migration is a significant concern because FCSEMS are tubular conduits and do not have anchoring flanges. The FCSEMS that are currently used were designed for drainage of a luminal structure such as the bile duct. There is a risk that these stents may migrate into the fluid collection, which would require entry into the cyst for removal and could be very technically challenging. One of the benefits of eliminating the step of tract dilation in our study was a reduction in the risk of stent migration due to the anchoring effect of stent compression, where the stent traversed the wall. However, after expanding to its full diameter, the FCSEMS can still migrate; therefore, we required that the study participants return very early for stent removal, at 7–10 days. We were concerned that there would be a significant risk of stent migration if the stents were left in place longer than 10 days.

### G&H What modifications could be made to the stents to improve their utility in this setting?

**KB** Metal stents were not designed for transluminal drainage, especially drainage of lumens that are not adherent to one another. We need stents that can create a lumen-to-lumen anastomosis and that can keep the lumens in apposition to each other. In addition, these stents should be short because they do not need to bridge a long stricture; they only need to bridge the walls of the 2 lumens they are connecting. This type of lumen-apposing anastomotic stent was described in an article I coauthored with Dr. Takao Itoi from Tokyo Medical University in Japan and others, in which 15 pancreatic pseudocysts and 5 gallbladders were internally drained. This stent is currently undergoing evaluation by the US Food and Drug Administration for use in the United States.

### G&H Is special training required to perform endoscopic drainage of fluid collections?

**KB** Yes. The first prerequisite is training in interventional endoscopic ultrasonography because this procedure should be performed under EUS guidance. Only EUS provides the ability to evaluate the distance between the fluid collection and the bowel wall, to detect the presence of wall adherence, and to identify vessels that may be interposed between the 2 lumens. It is necessary to see into and beyond the wall to perform this procedure safely and effectively. The second prerequisite is training in interventional transluminal procedures, such as conventional pseudocyst drainage, tract dilation, and transluminal stenting.

### G&H How does using EUS guidance for drainage compare with drainage via endoscopic retrograde cholangiopancreatography?

**KB** With endoscopic retrograde cholangiopancreatography, the endoscopist gains access to the pancreatic duct from the major or minor ampulla. Fluid collections must communicate with the pancreatic duct to be amenable to drainage through the ampulla. They should also be small because the drainage conduit is a single, small-diametered, plastic stent. I prefer to think of transpapillary and transmural drainage as complementary. A transmurally drained fluid collection may not resolve if there is a downstream stricture of the pancreatic duct. Transpapillary stenting may be required for the fluid collection to resolve.

### G&H What are the next steps in research in this area?

**KB** Management of WOPN is an area of great interest and current research. There are still many unanswered questions. It is unclear how aggressive endoscopists should be in the debridement of the necrosis and when and how frequently the debridement should be performed. In addition, the roles of mechanical necrosectomy versus irrigation need to be better defined as well as ways to optimize these procedures. We also need better tools for necrosectomy and to know when percutaneous or nasocystic catheter irrigation should be added to necrosectomy. In our unit, we perform vigorous irrigation of necrosis with several liters of saline, followed by 3% hydrogen peroxide, which helps break up necrotic tissue. Finally, research is underway using new stent designs such as the lumen-apposing anastomotic stent mentioned above that can serve as a port for endoscopic necrosectomy and enable easy repeat intubations of the cavity.

*Dr. Binmoeller is the Founder and Chief Medical Officer of Xlumena Inc.*

### Suggested Reading

- Weilert F, Binmoeller KF, Shah JN, Bhat YM, Kane S. Endoscopic ultrasound-guided drainage of pancreatic fluid collections with indeterminate adherence using temporary covered metal stents. *Endoscopy*. 2012;44:780-783.
- Itoi T, Binmoeller KF, Shah J, et al. Clinical evaluation of a novel lumen-apposing metal stent for endosonography-guided pancreatic pseudocyst and gallbladder drainage (with videos). *Gastrointest Endosc*. 2012;75:870-876.
- Gornals JB, Loras C, Mast R, Botargues JM, Busquets J, Castellote J. Endoscopic ultrasound-guided transesophageal drainage of a mediastinal pancreatic pseudocyst using a novel lumen-apposing metal stent. *Endoscopy*. 2012;44(suppl 2):E211-E212.
- Talreja JP, Shami VM, Ku J, Morris TD, Ellen K, Kahaleh M. Transenteric drainage of pancreatic-fluid collections with fully covered self-expanding metallic stents (with video). *Gastrointest Endosc*. 2008;68:1199-1203.
- Varadarajulu S, Phadnis MA, Christein JD, Wilcox CM. Multiple transluminal gateway technique for EUS-guided drainage of symptomatic walled-off pancreatic necrosis. *Gastrointest Endosc*. 2011;74:74-80.